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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,709	08/22/2001	Charles A. Morris	1533.0520001	6249

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EXAMINER	
PULLIAM, AMY E	
ART UNIT	**PAPER NUMBER**
1615	6

DATE MAILED: 08/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/933,709	Applicant(s) MORRIS ET AL.	
	Examiner Amy E Pulliam	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of the Amendment B, received May 21, 2002.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18, 19, 26, 27, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,234,695 to Hobbs *et al.*. Hobbs *et al.* disclose a vitamin E composition comprising a free flowing powder containing a vitamin E compound, and at least one flow agent selected from silicon dioxide, starch and others (c 9, claims 1 and 2). Further, Hobbs *et al.* teach that the vitamin E compound is present in between about 20-60% (c 3, l 61).

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant argues that the amendment requiring at least 65 weight percent vitamin negates the anticipatory reference. The examiner respectfully disagrees and points applicant to column 2, lines 14 and 15 of the reference, where it teaches that the vitamin can be present between 10 and 80 weight percent. Therefore, this rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18-28, and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Us Patent 4,486,435 to Schmidt *et al.*. Schmidt *et al.* teach a free-flowing, non-agglomerated, non-caking vitamin powder composition comprising about 45 to about 60 percent vitamin, about 2 to about 18 percent of a water insoluble carrier, about 0.2 to abut 2 percent hydrophobic silica, and other ingredients (c 8, l 15-22). Schmidt *et al.* further teach that the water insoluble carrier can be corn starch (c 8, line 32). Schmidt *et al.* also teach that the vitamin can be selected from vitamin A, D, E, K and mixtures thereof, as well as vitamin B_1, B_6, B_2, B_{12}, C and mixtures thereof (c 2, l 20-34). Lastly, Schmidt *et al.* teach that the vitamin composition of their invention is suitable for the preparation of tablets (c 1, l 49).

Schmidt *et al.* do not teach that the vitamin is specifically mixed tocopherols. However, Schmidt *et al.* do teach that the vitamin can be selected from a group including vitamin E. Furthermore, applicant admits in his own specification that vitamin E is a mixture of different molecular species, including d-alpha, d-beta, d-gamma, and d-delta, which vary based on the natural variation of the oil (applicant's specification, p 3, l 24-27). Therefore, it is the position of the examiner that based upon applicant's own admission, Schmidt's teaching of vitamin E suggests the limitations of the instant claims.

Schmidt *et al.* do not teach the specific density and surface area for the silica as claimed by applicant. However, it is the position of the examiner that with respect to the particular silica

particle size, absent a clear showing of criticality, the determination and manipulation of particular sizes is within the skill of the ordinary worker as part of the process of normal optimization. The burden is shifted to applicant to show why the difference in particle size or surface area renders a different result.

Lastly, the reference does not specifically discuss stability. However, it is the position of the examiner that absent evidence to the contrary, the formulation must provide appropriate stability, or it would be useless for its intended purpose. Furthermore, The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

One of ordinary skill in the are would have been motivated to make a vitamin composition comprising vitamin E, silica, and corn starch, based on the teachings of Schmidt. The expected result would be a free-flowing powder, non-sticking powder useful for pharmaceutical formulations. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant has amended the claims to recite "at least 65 to about 80 weight percent of at least one

vitamin." Applicant argues that the reference only teaches 60 weight percent vitamin, and therefore is not an anticipatory reference. The examiner agrees, and has therefore withdrawn the 102 rejection. However, the examiner maintains the rejection based on obviousness. The language of the reference states that the vitamin can be present at about 60 weight percent. The MPEP states, "The term 'about' used to define the area of the lower end of a mold as between 25 to about 45% of the mold entrance was held to be clear, but *flexible*. Ex parte Eastwood, 163 USPQ 316 (Bd. App. 1968)." Emphasis added. See MPEP section 2173.05(b)A. Therefore, the weight percent discussed by the reference can be held as clear, but flexible. The examiner contends that there has been no evidence provided by applicant to show a patentable distinction between 65 weight percent and about 60 percent. Particularly, because about 60 percent can be interpreted broadly, and could mean lightly higher than 60 percent. Additionally, in applicant's specification, ranges as large as 0.02 to 90% are disclosed. Although preferred embodiments narrowing the range to 50-80 are stated, there are no unexpected results disclosed. The burden is shifted to applicant to provide scientific data and comparative analysis to show unexpected results and patentable distinctions between the instant claims and the prior art. These distinctions must be a result of the specific weight percent. Therefore, this rejection is maintained.

Claims 22-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4,603,143 to Schmidt (US '143). US '143 discloses vitamin active powders which are more free-flowing and stable than conventional vitamin powders. US '143 teaches that the composition comprises at least one fat-soluble vitamin material and a silicon containing material

(c 1, l 38-45). US '143 also teaches that the vitamin be vitamin E, and further explains that vitamin E comprises a group of natural substances known as tocopherols (c 2, l 55-57). It is the position of the examiner that this disclosure reads on applicant's claim to mixed tocopherols. Furthermore, US '143 teaches that the silicon dioxide used in their composition has a density of around 0.2 g/cc (which is equivalent to 12.5 lbs./cu. ft.), and a particle size which passes through a 100 mesh sieve (c 3-4, table 1). (A 100 mesh sieve allows only particles which are smaller than 150 microns to pass through).

US '143 does not teach the specific particle size for the silica, as claimed by applicant. However, US '143 does teach that the particles are smaller than 150 microns. It is the position of the examiner that the determination of a particular particle sizes from within a broad range is within the skill of the ordinary worker as part of normal optimization. Additionally, US '143 does not teach the surface area of the silica. However, the burden is shifted to applicant to show that the silica disclosed by US '143 does not possess the same characteristics as the silica claimed by applicant. Lastly, US '143 does not specifically use the language mixed tocopherols in describing the vitamin to be used in their composition. However, as discussed in the anticipatory rejection, US '143 does teach that vitamin E is a group of natural substances known as tocopherol, and it further teaches that vitamin E can be used as the vitamin of the disclosed composition. Applicant admits in his own specification that vitamin E is a mixture of different molecular species, including d-alpha, d-beta, d-gamma, and d-delta, which vary based on the natural variation of the oil (applicant's specification, p 3, l 24-27).

Lastly, the reference does not specifically discuss stability. However, it is the position of the examiner that absent evidence to the contrary, the formulation must provide appropriate

stability, or it would be useless for its intended purpose. Furthermore, The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Therefore, it is the position of the examiner that based upon applicant's own admission, the disclosure in US '143 teaching the use of vitamin E suggests the limitations of the instant claims. One of ordinary skill in the art would have been motivated to make a vitamin composition comprising vitamin E and silica. The expected result would be a free-flowing, fat-soluble vitamin powder with improved stability. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been fully considered but are not found persuasive. See the discussion of arguments following the first rejection.

Claims 18-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,234,695 to Hobbs *et al.*. Hobbs *et al.* are discussed above as teaching a vitamin E composition

comprising a free flowing powder containing between 20-60% of a vitamin E compound and at least one flow agent selected from a group including silicon dioxide and starch.

Hobbs *et al.* do not teach that the vitamin is specifically mixed tocopherols. However, Hobbs *et al.* do teach that the vitamin can be selected from a group including vitamin E. Furthermore, applicant admits in his own specification that vitamin E is a mixture of different molecular species, including d-alpha, d-beta, d-gamma, and d-delta, which vary based on the natural variation of the oil (applicant's specification, p 3, l 24-27). Therefore, it is the position of the examiner that based upon applicant's own admission, Hobb's teaching of vitamin E suggests the limitations of the instant claims.

Hobbs *et al.* do not teach the specific density and surface area for the silica as claimed by applicant. However, it is the position of the examiner that with respect to the particular silica particle size, absent a clear showing of criticality, the determination and manipulation of particular sizes is within the skill of the ordinary worker as part of the process of normal optimization. The burden is shifted to applicant to show why the difference in particle size or surface area renders a different result.

Lastly, the reference does not specifically discuss stability. However, it is the position of the examiner that absent evidence to the contrary, the formulation must provide appropriate stability, or it would be useless for its intended purpose. Furthermore, The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than

those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

One of ordinary skill in the are would have been motivated to make a vitamin composition comprising vitamin E, silica, and corn starch, based on the teachings of Hobbs *et al.*. The expected result would be a free-flowing powder, non-sticking powder useful for pharmaceutical formulations. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been considered but are not found to be persuasive. Applicant has amended the claims to recite "at least 65 to about 80 weight percent of at least one vitamin." Applicant argues that the reference only teaches 60 weight percent vitamin, and therefore is not an anticipatory reference. The examiner agrees, and has therefore withdrawn the 102 rejection. However, the examiner maintains the rejection based on obviousness. Applicant provides ranges in the specification as broad as 0.02 to 90 weight percent. Although preferred embodiments are described which recite narrower ranges, there are no patentable distinctions disclosed as a result of a smaller range. It is the position of the examiner that 60 weight % and 65 weight percent are obvious variants of one another. Furthermore, the burden has been shifted to applicant to supply unexpected results and patentable distinctions which result from the slight difference in weight percent. Therefore, this rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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